UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,938	11/10/2004	Seishi Kato	2004-1562A	4951

513 7590 12/12/2007

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
LUNDGREN, JEFFREY S	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
12/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,938	KATO ET AL.	
	Examiner	Art Unit	
	Jeff Lundgren	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *9-12 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 13-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-8 and 13-16, in the reply filed on October 5, 2007, is acknowledged.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 13-16 are anticipated by Nilsen:

Claims 1-8 and 13-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nilsen et al., U.S. Patent No. 6,013,447, issued on January 11, 2000.

Claim 1 is directed towards a cell population with identification codes, which is a population of cells that can be distinguished from one another based on a difference in luminescent signals emitted by luminescent substances, wherein the difference in the luminescent signals is caused by either or both: (a) 2 or more different luminescent properties; and (b) 2 or more different luminescent sites.

Nilsen is directed towards method for the identification of affector RNA molecules, such as ribozymes, external guide sequences, anti-sense RNA, and triple helix-forming RNA, that inhibit expression of target RNA. The method identifies functional affector RNA molecules by screening or selecting for those RNA molecules that inhibit expression of a fusion transcript, which includes the sequence of an RNA molecule of interest, from a library of potential affector RNA molecules.

As required by claim 1, Nilsen teaches a population of cells that have two or more luminescent properties and two or more different sites:

> "The vectors include a ***reporter gene encoding the fusion transcript including the RNA molecule of interest and RNA encoding the reporter protein***. The vectors also include ***a second reporter gene encoding a second reporter protein***. Expression of the second reporter protein can be used both to detect transformation or transfection of the vector into cells and as a control for effects on the expression of the first reporter protein that are not due to inhibition of expression of the RNA molecule of interest. The vector also encodes an affector RNA molecule targeted to the RNA of interest. The method preferably uses a set of these vectors ***where each vector in the set encodes a different affector RNA molecule, each targeted to a different site in the RNA of interest***. The set of vectors is transformed or transfected into appropriate cells, and the cells are screened or selected for expression of the second reporter protein. These cells are then screened or selected for those cells which do not express the first reporter protein, or express the reporter protein only at a low level. These cells harbor the most efficient affector RNA molecules which then can be identified by characterizing the vectors in the cells."

Nilsen, col. 3, lines 37-57 (emphasis added); and:

> "A set of the vectors encoding a ***first reporter gene encoding GFP*** as reporter protein A, a second reporter gene, and targeting gene encoding a library of EGS or ribozyme molecules as the affector RNA molecules are amplified by growing the mixed population in E. coli. A fixed concentration of mixture of plasmids is complexed with an appropriate carrier (for example, lipid, calcium phosphate, DEAE dextran) and ***delivered to mammalian cells***. At the peak day of expression (usually day two), the level of expression of GFP and the second reporter are measured by FACS sorting. ***The expression of the second reporter (for example, CD4) is measured at a wavelength that does not overlap with GFP fluorescence spectrum. Typically, an antibody conjugated with a fluorescent tag is used*** and directed against the second reporter protein to monitor the level of expression of the second reporter. The antibody is incubated with the cells, excess antibody is washed off, and the fluorescence is monitored at a wavelength different from GFP. The ratio of GFP expression to second reporter expression is used as a measure to determine the degree of inhibition of expression of the target sequence. The cells are lysed, plasmid extracted, amplified in bacteria, and sequenced to identify the EGS/ribozyme associated with the cell population."

Nilsen, col. 18, lines 40-62 (emphasis added).

Accordingly, claim 1 is anticipated.

As in claim 2, Nilsen discloses GFP and fluorescently tagged antibodies (see captioned sections above).

As in claim 3 and 13, Nilsen teaches that at least "part" of the cells produce a fusion protein of a fluorescent protein and a localization signal peptide (see captioned sections above; see also col. 17, lines 65 to col. 18, line 4, where the cell surface protein is shown to be a reporter protein).

As in claim 4, each of the cells has a different property represented by the different reporter genes (see captioned sections above); and as in claim 5, it is the expression of a different target protein.

As in claims 6 and 7, Nilsen discloses eukaryotic cells and mammalian cells (see captioned section above).

As in claims 8 and 14-16, Nilsen teaches that the mixture is complexed with a commercially available preparation of lipid or calcium phosphate and transfected to cells plated in 96 wells.

Claims 1 and 4 are anticipated by Fulwyler:

Claims 1 and 4, are rejected under 35 U.S.C. § 102(b) as being anticipated by Fulwyler, U.S. Patent No. 4,499,052, issued on February 12, 1985

Claim 1 is directed towards a cell population with identification codes, which is a population of cells that can be distinguished from one another based on a difference in luminescent signals emitted by luminescent substances, wherein the difference in the luminescent signals is caused by either or both: (a) 2 or more different luminescent properties; and (b) 2 or more different luminescent sites.

Fulwyler states in the Abstract the scope of his invention:

> "A method of distinguishing multiple subpopulations of cells from a single sample of cells of a variety of types comprises labeling particles with two or more marking agents. These particles are marked in a plurality of different pre-selected ratios of the agents ranging between zero percent and one hundred percent of each agent. Each such agent has distinguishing, quantifiable marking characteristics. The differently labeled particles are mixed with cells suspected of having specific receptors for the differently labeled particles. Each cell is analyzed to

> determine the ratio of any two identifiable marking characteristics associated with each cell so that it can be classified in a subpopulation category if its ratio of marking characteristics is related to one of the pre-selected ratios of marking agents."

and:

> "The preparations of Example 2 are repeated, except that conventional FITC (fluorescein isothiocyanate) and RITC (rhodamine isothiocyanate) labeled antibodies are used in place of the fluorescein-containing and rhodamine-containing polymers. Results of analyzing these cells in a flow-through, dual fluorescence cytometer, would be substantially similar to the results shown in Example 1."

Fulwyler, col. 7, lines 61-68.

Applicants' claim 1 encompasses the cell of Fulwyler because Applicants claims are directed to cells that can be distinguished from each other by two fluorescent signal in two different locations. The fact that Fulwyler applies the fluorescent tags externally is irrelevant for claim 1. Accordingly, claim 1 is anticipated.

As in claim 4, each cell in the library population of Fulwyler is different.

Conclusions

No claim is allowable.

If Applicants should amendment the claims, a complete and responsive reply will clearly identify where support can be found in the disclosure for each amendment. Applicants should point to the page and line numbers of the application corresponding to each amendment, and provide any statements that might help to identify support for the claimed invention (*e.g.*, if the amendment is not supported *in ipsis verbis*, clarification on the record may be helpful). Should Applicants present new claims, Applicants should clearly identify where support can be found in the disclosure.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jeff Lundgren whose telephone number is 571-272-5541. The Examiner can normally be reached from 7:00 AM to 5:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Schultz, can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL

/Jon D. Epperson/
Primary Examiner, AU 1639